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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,437	12/20/1999	ISA ODIDI	10914-11	7273

7590 06/15/2004
DINSMORE & SHOHL
255 EAST FIFTH STREET
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CINCINNATI, OH 45202

EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/15/2004

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,437

Applicant(s)

ODIDI ET AL.

Examiner

Retford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 32.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Acknowledgement: Applicant's Amendment filed April 13, 2003 is acknowledged.

Status of Claims

1. The status of the claims is as follows:

Claims 1-3 and 5-34 are pending in view of applicant's amendment.

Claim Rejections-35 USC Sec 103

2. Claim 1-3 and 5-34 remain rejected under 35 USC 103(a) as being unpatentable over US Patent 5,000, 962 to Sagekar et al, in view of US 5, 162, 117 to Stupak et al and further in view of US Patent 6, 083, 532 to Zhang et al; as set forth in the previous office action.

3. The Declarations Under 37 CFR 1.132, signed by inventors and submitted with Amendment dated December 4, 2003 have been considered. It is the position of the examiner that scope of the differential release rates of drug incorporated within polymers presented in the Declarations Under 37 CFR 1.132 is different from the scope of the claims (1-3) and (5-22) as previously presented. As set forth in the previous office action, the scope of the claims in regards to controlled release of the drug designed to provide immediate release dosage and a second delayed dosage in the gastrointestinal tract can routinely be determined by one of ordinary skill in the art.

4. The remaining claims (i.e. claims 23-34) are directed toward process claims and these fall outside the scope of the Declarations Under 37 CFR 1.132 as presented. Furthermore, it is the position of the examiner that the process of manufacture of controlled release composition of active substance involving mixing of ingredients, blending, granulating and drying are procedures than can routinely be varied by one of ordinary skill to obtain formulations that yield

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expected rates of release. Barring unexpected results the procedures are considered routine laboratory manipulations.

Response To Arguments

5. Applicants arguments filed April 13, 2004 have been fully considered but they are found not persuasive.

6. Claim 1-3 and 5-34 remain rejected under 35 USC 103(a) as being unpatentable over US Patent 5,000, 962 to Sagekar et al, in view of US 5, 162, 117 to Stupak et al and further in view of US Patent 6, 083, 532 to Zhang et al; as set forth in the previous office action.

7. Applicants argue that they have conducted experiments and have discovered improvement over the prior art in that compositions of (a) hydroxyethylcellulose (HEC) and hydroxypropylmethyl cellulose (HPMC) together, (b) hydropropylmethyl cellulose alone and (c) hydroxyethyl cellulose alone; provide different rates of release of drug. Applicants also argue that the composition provides immediate dosing of an active agent and delayed dosing of the active agent.

8. In response to this argument, as was set forth in the previous office action, Sangekar et al (Patent '962) discloses hydrophilic polymers that can be used alone or in combination for long acting release formulation; the combination included the use of hydroxypropylmethyl cellulose and hydroxyethylcellulose (abstract and col 2, lin 57-65). Patent '962 discloses the use of polymers that can be used with polymeric binder (col 3, lin 55). Also, Zhang et al (Patent '532) discloses a composition wherein a mixture of hydroxypropylmethyl cellulose, hydroxypropyl ethyl cellulose, hydroxy propyl cellulose hydroxy ethyl cellulose and methyl cellulose (col 3, lin 45-65 and col 4, lin 65 continuing to col 5, lin 1-3). More importantly, similar to applicant's use

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of hydroxyethylcellulose (HEC) and hydroxypropylmethyl cellulose (HPMC) together, Patent '532 also discloses that the drug release rate can be adjusted by changing the amount of one or more of the component polymers (abstract). Therefore applicant's results presented in the declarations are not unexpected based upon the combination of polymers that were tested.

9. Applicants argue that the differential dissolution rates observed in the three compositions used in the experiments in the Second Declaration under 37 CFR 1.132 are significant especially with high potency drugs where both immediate and delayed release are necessary and that the declaration shows unexpected results over the prior art.

10. In response, Stupak et al (Patent '117) discloses controlled release of flutamide designed to provide immediate release dose and a second delayed release dose in pulsatile manner (abstract). The combination of the disclosures in the prior art cited (i.e. Patent '962, Patent '532 and Patent '117) permits one of ordinary skill in the art to design an experiment to obtain a biphasic controlled release of drug and thereby expect the results presented in the declaration because as previously discussed in paragraph 8, drug release rate can be adjusted by changing the amount of one or more of the component polymers.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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